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EXAMINER	
HENRY, MICHAEL C	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/635,928	VENKATARAMAN, BALAJI	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-12,15-19,22-31 and 33-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 7-12, 15-19, 22-31, 33-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 04/09/07.

The amendment filed 04/09/07 affects the application, 10/635,928 as follows:

Claims 15, 22, 24, 41-45 have been amended. Claims 46, 47 have been canceled.

Applicant's amendment has overcome the 112 2nd rejections of the prior office action mailed 01/11/07. The rejections of the Composition Claims Under 35 U.S.C. § 103 are maintained. The Applicant's amendment of the method claims necessitated the new grounds of rejections of the method claims (under 35 U.S.C. 102 and 103) made by applying Bell et al.'s prior art reference.

The responsive to applicants' arguments is contained herein below.

Claims 1-5, 7-12, 15-19, 22-31, 33-45 are pending in application

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 22, 44, 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Bell et al. (WO 99/65337).

In claim 15, applicant claims "A method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in an individual comprising administering to the individual an effective amount of a composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Bell et al. disclose applicant's method of treating osteoporosis

(reducing the risk of osteoporosis) in an individual (post-menopausal women or women lacking their ovaries) comprising administering to the individual an effective amount of a composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see claims 21 and 1, see also abstract). It should be noted that the applicant's method **comprises** administering the said composition that consist of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and therefore does not exclude the use or administration of additional ingredients or components to treat said osteoporosis or conditions. Claim 22 which is drawn to the method of claim 15, wherein the hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss is caused by specific conditions including menopause, is also anticipated by Bell et al (see claims 21 and 1). It should be noted that the applicant's method **comprises** administering the said composition that consist of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and therefore does not exclude the use or administration of additional ingredients or components to treat said osteoporosis or conditions. Furthermore, applicant's composition is also for osteoporosis caused by menopause. In addition, it should be noted that the cause of the osteoporosis as (recited by applicant) does not further limit the treatment of the osteoporosis.

In claim 44, applicant claims a method comprising administering to a menopausal woman or a postmenopausal woman an effective amount of a composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6, wherein the amount is effective to treat hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in the menopausal woman or the postmenopausal woman. Bell et al. disclose applicant's method of treating osteoporosis (reducing the risk of osteoporosis) in an individual (post-menopausal women or women lacking their ovaries) comprising administering to the individual an effective amount of a composition

consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see claims 21 and 1). It should be noted that the applicant's method **comprises** administering the said composition that consist of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and therefore does not exclude the use or administration of additional ingredients or components to treat said osteoporosis or conditions.

Claim 45 is drawn to the method of Claim 44, wherein the hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in the menopausal woman or the postmenopausal woman is caused by menopause, smoking, hysterectomy, ovariectomy or cancer chemotherapy, or treatment of the menopausal woman or the postmenopausal woman with an estrogen, an androgen, an estrogen-androgen combination, an estrogen-progesterone combination, a steroid or a drug that affects the reproductive system. Bell et al. disclose applicant's method of treating osteoporosis (reducing the risk of osteoporosis) in an individual (post-menopausal women or women lacking their ovaries) comprising administering to the individual an effective amount of a composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see claims 21 and 1). It should be noted that the applicant's method **comprises** administering the said composition that consist of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and therefore does not exclude the use or administration of additional ingredients or components to treat said osteoporosis or conditions. Furthermore, applicant's composition is also for osteoporosis caused by menopause. In addition, it should be noted that the cause of the osteoporosis as (recited by applicant) does not further limit the treatment of the osteoporosis.

Claims 16-19, 24, 30, 33, 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell et al. (WO 99/65337).

In claim 15, applicant claims "A method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in an individual comprising administering to the individual an effective amount of a composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 16-19 which are further limitations of claim 15, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 24 is drawn to a method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss in an individual comprising administering to the individual an effective amount of a vitamin composition consisting of calcium, vitamin D, folic acid, hydroxocobalamin and vitamin B6. Claims 30, 33, 41-45 are drawn to said method of treating hot flashes, osteoporosis, endometriosis, hyperhomocystineamia, or bone loss using specific amounts or quantities of the components in the composition.

Bell et al. disclose a method of treating osteoporosis (reducing the risk of osteoporosis) in an individual (post-menopausal women or women lacking their ovaries) comprising administering to the individual an effective amount of a composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 (see claims 21 and 1). It should be noted that the applicant's method **comprises** administering the said composition that consist of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and therefore does not exclude the use or administration of additional ingredients or components to treat said osteoporosis or conditions. Furthermore, Bell et al. disclose that different ranges of amounts or quantities of the components

(calcium, vitamin D, folic acid, vitamin B12 and vitamin B6) of the composition can be used (see page 2, line 30 to page 3, line 15). Bell et al. also disclose that the composition can be formulated with other vitamins, minerals and nutrients (see page 10, lines 5-7). Bell et al. disclose that vitamin D can be used in the forms such as vitamin D_3 and D_2 (see page 5, lines 3-12).

The difference between applicant's claimed method and the method of Bell et al. is that applicant's uses the hydroxocobalamin form of vitamins B12 and the specific amounts or quantities of the individual components of the composition. However, Hydroxocobalamin is a form of vitamin B12 (which is injectable) with similar effect as vitamin B12 and is used interchangeable with vitamin B12 based on factors such as mode or route by which it is to be administered (e.g., by injection). In fact, Hydroxocobalamin is an active form of vitamin B12.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Bell et al. to treat osteoporosis in post-menopausal women or women lacking their ovaries by administering Bell et al.'s composition and to use any form of B12 such as hydroxocobalamin and different amounts of said components, depending on factors such as the severity of the osteoporosis and the mass or age of the woman being treated.

One having ordinary skill in the art would have been motivated in view of Bell et al. to treat osteoporosis in post-menopausal women or women lacking their ovaries by administering Bell et al.'s composition and to use any form of B12 such as hydroxocobalamin and different amounts of said components, depending on factors such as the severity of the osteoporosis and the mass or age of the woman being treated. It should also be noted that, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-

known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7-12, 23, 25-29, 31, 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Kostic (Archiv fuer Gynaekologie (1965), 202 (1), pages 506-509).

In claim 1, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6, and specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 23 is drawn to composition consisting of calcium, vitamin D, folic acid, hydroxycobalamin (vitamin B12) and vitamin B6. Dependent claims 25-29 are drawn to specific amounts of hydroxocobalamin (vitamin B12) and folic acid.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1). Paradissis et al. disclose that their composition maximizes or optimizes fetal development and maintain the mothers health during the three trimesters of pregnancy (see abstract)

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Kostic to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific

pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women and depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the pregnant women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

In claim 35, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin C." In claim 36, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and iron." In claim 37, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6, vitamin C and iron." Dependent claims 38-40 are drawn to said composition wherein vitamins B12 is hydroxocobalamin.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see col.7, line 45 to col. 8, line 16). Furthermore, Paradissis et al. disclose that this composition may comprise vitamin C and

iron (see col.7, line 45 to col. 8, line 16) and that other component including vitamin E, Vitamin B_2 and B_3 may be absent (i.e., 0 mg) from the said composition (see col.7, line 45 to col. 8, line 16).

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Kostic to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, child birth and/or may be a detriment to said pregnant women and depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the pregnant women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Claims 1-5, 7-12, 23, 25-29, 31, 34-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradissis et al. (US 5,494,678) in view of Boros et al. (Proceedings of the American Association for Cancer Research Annual Meeting, (March, 2000) No. 41, pp. 666. print. Meeting info.: 91st Annual Meeting of the American Association for Cancer Research. San Francisco, California, USA. April 01-05, 2000. ISSN: 0197-016X) or Boros (Anticancer Research, (2000) Vol. 20, No, No. 3 B, Pages 2245-2248).

In claim 1, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6." Claims 2-5, 7-12, 31, 34 which are further limitations of claim 1, are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6, and specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3). Claim 23 is drawn to composition consisting of calcium, vitamin D, folic acid, hydroxycobalamin (vitamin B12) and vitamin B6. Dependent claims 25-29 are drawn to specific amounts of hydroxocobalamin (vitamin B12) and folic acid. Claim 35 is drawn to a composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin C." In claim 36, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and iron." In claim 37, applicant claims "A composition consisting of calcium, vitamin D, folic acid, vitamin B12, vitamin B6, vitamin C and iron." Dependent claims 38-40 are drawn to said composition wherein vitamins B12 is hydroxocobalamin.

Paradissis et al. disclose a composition for treating pregnant women comprising calcium, vitamin D, folic acid, vitamin B12, vitamin B6 and vitamin B1 (see abstract and claim 1). Paradissis et al. disclose that their composition maximizes or optimizes fetal development and maintain the mothers health during the three trimesters of pregnancy (see abstract). Furthermore, Paradissis et al. disclose that this composition may comprise vitamin C and iron (see col.7, line 45 to col. 8, line 16) and that other component including vitamin E, Vitamin B_2 and B_3 may be absent (i.e., 0 mg) from the said composition (see col.7, line 45 to col. 8, line 16).

The difference between applicant's claimed composition and the composition of Paradissis et al. is that applicant's composition does not contain vitamin B1.

Boros et al. disclose that vitamin B1 promotes cancer growth (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

Boros discloses that vitamin B1 excess thiamine supplementation contributes to increase cancer rates by enhancing tumor cell proliferation in people of different countries (see abstract and entire article). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made in view of Paradissis et al. and Boros et al. or Boros to prepare Paradissis et al.'s composition (for pregnant women) and to exclude vitamin B1 in order to administer the composition to pregnant women especially women with the high-risk pregnancies (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered.

One having ordinary skill in the art would have been motivated in view of Paradissis et al. and Boros et al. or Boros to prepare Paradissis et al.'s composition (for pregnant women) and

to exclude vitamin B1 in order to administer the composition to pregnant women especially women with the high-risk pregnancies (as claimed by applicant) so as to prevent the promotion of possible cancer or tumor conditions in said pregnant women due to vitamin B1, depending on factors such as the medical history, medical health and the daily medications been taken by the women to which the vitamin composition is to be administered. It should be noted that claims 2-5, 7-12, 23, 25-29, 31, 34 which are drawn to specific amounts of calcium, vitamin D, folic acid, vitamin B12 and vitamin B6 and, specific kinds of vitamins B12 (i.e. hydroxocobalamin) and vitamin D (i.e. vitamin D3) are also encompassed by the aforementioned rejection since the amount or quantity of the components used in the composition depends on factor like the severity of the condition and the mass or age of the pregnant women being treated. In addition, the preparation or alteration of different vitamins and/or minerals formulations consisting of a combination of well-known art recognized vitamins and/or minerals to treat particular conditions, deficiencies, illnesses is also within the purview of an ordinary artisan.

Response to Amendment

Applicant's arguments with respect to claim 1 have been considered but are not found convincing.

The applicant argues that applicant's composition does not contain vitamin B1 and is limited by the use of the language consisting of. However, the rejections that renders applicant's claimed composition unpatentable are set forth above.

The applicant argues that Kostic uses doses of vitamin B1 (100 mg) that are 50 to 100 times greater than disclosed by Paradissis (1-2 mg). Kostic, in the short three line abstract

provided, gives 100 mg of vitamin B1 to women in labor after cervical dilation reached 3-4 cm in order to increase the force and frequency of uterine contractions.

However, although Kostic discloses the use of larger doses of vitamin B1 that increases the force and frequency of uterine contractions, a skilled artisan (in view of Kostic) would realize that smaller doses or concentrations of the said vitamin B1 may have the same effect of increasing the force and frequency of uterine contractions and that even if the effect is less then said less effect would be multiplied or more pronounced in the case of a high-risk pregnant woman. Also, it would be obvious to a skilled artisan that a smaller dose or amount of the vitamin B1 would have an even more pronounced effect of increasing the force and frequency of uterine contractions in the case of a high-risk pregnant depending on her weigh, age and physical condition. Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as originally claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women (see also, the above rejection).

The applicant argues that Paradissis's compositions include vitamin B 1 and are designed to maximize fetal development and maternal health during each trimester of pregnancy (see Abstract), not to accelerate uterine contractions. One of ordinary skill in the art would not combine Kostic and Paradissis as they are addressing completely different issues. However, a skilled artisan would alter Paradissis et al. vitamin composition (in view of Kostic) by removing

vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy so as to prevent any possible accelerated or increased uterine contractions (like that caused by vitamin B1) that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women (see also, the above rejection). Thus, One of ordinary skill in the art would combine Kostic and Paradissis. Also, it should also be noted that both Kostic and Paradissis addresses the same issue of treating pregnant women.

The applicant argues that One of ordinary skill in the art who might use Paradissis's composition for its intended purpose would not look to art teaching acceleration of labor by using 50-100 times the amount of vitamin B1 in Paradissis's composition, and then conclude that the 1 to 2 mg amount of vitamin B 1 in Paradissis should be removed because it might accelerate labor. Paradissis's composition, which includes vitamin B1, does not accelerate labor and cause premature birth. Accelerating labor would render Paradissis's composition inoperable for its intended purpose and could cause premature delivery, thereby endangering the health of the fetus and mother. However, although Kostic discloses the use of larger doses of vitamin B1 that increases the force and frequency of uterine contractions, a skilled artisan (in view of Kostic) would realize that smaller doses or concentrations of the said vitamin B1 may have the same effect of increasing the force and frequency of uterine contractions and that even if the effect is less then said less effect would be multiplied or more pronounced in the case of a high-risk pregnant woman. Also, it would be obvious to a skilled artisan that a smaller dose or amount of the vitamin B1 would have an even more pronounced effect of increasing the force and

frequency of uterine contractions in the case of a high-risk pregnant depending on her weight, age and physical condition. Consequently, a skilled artisan would alter Paradissis et al. vitamin composition (in view of Kostic) by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as originally claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women (see also, the above rejection).

The applicant argues that Kostic does not disclose, teach or suggest that vitamin B1 is not required in Paradissis's composition. However, although Kostic does not disclose, teach or suggest that vitamin B1 is not required in Paradissis's composition, Kostic discloses that large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition (in view of Kostic) by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women (see also, the above rejection).

The applicant argues that Paradissis's composition, which includes vitamin B1, does not accelerate labor and cause premature birth. However, although Paradissis's composition, which includes vitamin B1, does not accelerate labor and cause premature birth, Kostic discloses that

large doses of vitamin B1 (e.g., 100 mg) administered to pregnant women increases uterine contractions in force and frequency (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition (in view of Kostic) by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women (see also, the above rejection).

The applicant argues that accelerating labor would render Paradissis's composition inoperable for its intended purpose and could cause premature delivery, thereby endangering the health of the fetus and mother. Consequently, a skilled artisan would alter Paradissis et al. vitamin composition (in view of Kostic) by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with specific pregnancy conditions such as women with the high-risk pregnancy (as originally claimed by applicant) so as to prevent increased uterine contractions that could cause adverse effects or conditions such as premature labor, premature child birth and/or may be a detriment to said pregnant women (see also, the above rejection).

The applicant argues that Applicant's claimed composition is effective. Applicant conducted a study concerning administration of one embodiment of the present invention to post menopausal women. This embodiment consisted of folic acid (1.6 mg), vitamin B12 (425 mcg), vitamin B6 (25 mg), vitamin D (400 IU) and calcium (400 mg), administered in two pills per day. Plasma homocysteine levels were measured before and six weeks after administration of the vitamin composition. The results show greater than a 20% reduction in plasma homocysteine levels in the postmenopausal women receiving the vitamin. These striking and unexpected results demonstrate the remarkable efficacy of Applicant's claimed vitamin composition. The cited art, alone or in combination, does not teach, suggest or provide motivation to make

Applicant's composition, as claimed, which is efficacious at least in post-menopausal women to reduce homocysteine levels.

However, Bell et al. disclose that the components folic acid, vitamin B12 and vitamin B6 act synergistically to reduce homocysteine in blood serum (see page 9, lines 2-17). Consequently, it is obvious to expect that a combination comprising the components folic acid, vitamin B12 and vitamin B6 to act synergistically to reduce homocysteine in the blood. Furthermore, It is known that the said combined components act synergistically in the manner stated above (e.g, see US 6,040,333, col. 5, lines 55-62).

The applicant argues that one of ordinary skill in the art of Applicant's claimed invention would not look to Boros et al. using tumor bearing mice in the field of cancer cell biology for any guidance, suggestion or motivation to remove vitamin B1 from Paradissis's composition and derive Applicant's claimed compositions. Boros et al. does not provide any motivation or suggestion to modify Paradissis's composition. Boros et al. is improperly combined with Paradissis in this rejection. However, Boros et al. disclose that vitamin B1 promotes cancer growth (see abstract). Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as originally claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions. It should also be noted that it is obvious to a skilled artisan and well known in the art that agents or substances that cause or promotes cancer in mammals such as mice also causes or promotes cancer in humans.

The applicant argues that Paradissis discloses vitamins for pregnant women at different trimesters to promote fetal and maternal health. Paradissis's vitamin compositions comprise vitamin B1 and other ingredients for this purpose. Paradissis does not provide excess vitamin B1 in its compositions and does not administer vitamins in order to potentially contribute to an increased risk of cancer. Paradissis includes 1.0 to 2.0 mg of vitamin B1 in the vitamin

compositions and does not administer excess vitamin B1. Boros states the RDA for thiamine in women is 1.0 mg (page 2245, first paragraph after the abstract). However, Paradissis includes 2.0 mg whichis an excess vitamin B1 since Boros states the RDA for thiamine in women is 1.0 mg.

Also, a skilled artisan would realize that smaller doses or concentrations of the said vitamin B1 may have the same effect of promoting cancer and that even if the effect is less then said less effect would be multiplied or more pronounced in the case of a high-risk pregnant woman with cancer. Also, it would be obvious to a skilled artisan that a smaller dose or amount of the vitamin B1 would have an even more pronounced effect of promoting cancer in the case of a high-risk pregnant woman depending on her weight, age and physical condition. Consequently, a skilled artisan would alter Paradissis et al. vitamin composition by removing vitamin B1 from Paradissis et al. vitamin composition in order to administer the composition to pregnant women especially women with the high-risk pregnancy conditions (as claimed by applicant) and pregnant women with cancer or tumor malignancies or conditions.

The Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

SAJ 9/4/07

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September 1, 2007.